UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

| APPLICATION NO.   | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|---------------------------------|----------------------|----------------------|------------------|
| 10/580,248  | 07/20/2006                      | Mimi Adachi          | 64517.000003         | 6084             |
|   | 7590 12/29/2006<br>VILLIAMS LLP | • EXAMINER           |                      |                  |
| INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109 |                                 |                      | SGAGIAS, MAGDALENE K |                  |
|   |                                 |                      | ART UNIT             | PAPER NUMBER     |
|   |                                 |                      | 1632                 |                  |
| · .   | ·                               | ±                    |                      |                  |
| SHORTENED STATUTOR  | Y PERIOD OF RESPONSE            | MAIL DATE            | DELIVERY MODE        |                  |
| 31 DAYS 12/29/2006  |                                 | 12/29/2006           | PAPER                |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|   | Application No.  | Applicant(s)   |
|---|--|--|
|   | 10/580,248   | ADACHI ET AL.  |
| Office Action Summary   | Examiner   | Art Unit   |
|   | Magdalene K. Sgagias   | 1632   |
| The MAILING DATE of this communication ap<br>Period for Reply   |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).   | DATE OF THIS COMMUNICA<br>136(a). In no event, however, may a rep<br>will apply and will expire SIX (6) MONTHE, cause the application to become ABAN | ATION.  ly be timely filed  IS from the mailing date of this communication.  NDONED (35 U.S.C. § 133). |
| Status  |  |  |
| 1) Responsive to communication(s) filed on 20 C 2a) This action is FINAL. 2b) This 3) Since this application is in condition for alloware closed in accordance with the practice under the condition of the condi | s action is non-final.<br>ance except for formal matter  | •  |
| Disposition of Claims   |  |  |
| 4) ☑ Claim(s) 1-33 is/are pending in the application 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☑ Claim(s) 1-33 are subject to restriction and/or   | awn from consideration.  |  |
| Application Papers  |  | •  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomposite and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the      | cepted or b) objected to by<br>drawing(s) be held in abeyance<br>ction is required if the drawing(s)   | e. See 37 CFR 1.85(a).<br>is objected to. See 37 CFR 1.121(d).   |
| Priority under 35 U.S.C. § 119  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat * See the attached detailed Office action for a list  | ts have been received.<br>ts have been received in Appority documents have been re<br>nu (PCT Rule 17.2(a)).   | olication Noeceived in this National Stage   |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)   | Paper No(s)/I  | nmary (PTO-413)<br>Mail Date<br>rmal Patent Application  |
| Paper No(s)/Mail Date   | 6) Other:  | •  |

Application/Control Number: 10/580,248

Art Unit: 1632

## **DETAILED ACTION**

Claims 1-33 are pending.

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 4-12, 15-25, 31drawn to a method for proliferating cardiomyocytes comprising a step of introducing (a) cyclin, (b) cyclin-dependent kinase, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function or action of Cip/Kip family protein, or a nucleic acid that inhibits the production of Cip/Kip family protein, into cardiomyocytes, and a step of subsequently culturing or maintaining said cells, wherein the factor that inhibits the production, function or action of Cip/Kip family protein is an encoding protein factor in vitro.

Group II, claim(s) 1, 2, 4-8, 13-16, 17-21, 26-28, 31 drawn to a method for proliferating cardiomyocytes comprising a step of introducing (a) cyclin, (b) cyclin-dependent kinase, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function or action of Cip/Kip family protein, or a nucleic acid that inhibits the production of Cip/Kip family protein, into cardiomyocytes, in vivo, and a step of subsequently culturing said cells, wherein the nucleic acid that inhibits the production of Cip/Kip family proteins is siRNA specific to a gene encoding the Cip/Kip family protein in vitro.

Group III, claim(s) 1, 3-12, 15-25, 29-33 drawn to a method for proliferating cardiomyocytes comprising a step of introducing (a) cyclin, (b) cyclin-dependent kinase, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function or action of Cip/Kip family protein, or a nucleic acid that inhibits the production of Cip/Kip family protein, into cardiomyocytes, and a step of subsequently culturing or maintaining said cells, wherein the factor that inhibits the production, function or action of Cip/Kip family protein is an encoding protein factor in vivo.

Group IV, claim(s) 1, 3-8, 13-21, 26-33 drawn to a method for proliferating cardiomyocytes comprising a step of introducing (a) cyclin, (b) cyclin-dependent kinase, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function or action of Cip/Kip family protein, or a nucleic acid that inhibits the production of Cip/Kip family protein, into cardiomyocytes, in vivo, and a step of subsequently culturing said cells, wherein the nucleic acid

Application/Control Number: 10/580,248

Art Unit: 1632

that inhibits the production of Cip/Kip family proteins is siRNA specific to a gene encoding the Cip/Kip family protein in vivo.

Group V, claim(s) **17-25**, drawn to a vector comprising (a) a cyclin gene (b) a cyclin-dependent kinase gene, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function, or action of Cip/Kip family protein or a nucleic acid sequence that inhibits the production of Cip/Kip family protein, wherein the factor that inhibits the production, function or action of Cip/Kip family protein is an encoding protein factor.

Group VI, claim(s) 17-21, 26-28 drawn to a vector comprising (a) a cyclin gene (b) a cyclin-dependent kinase gene, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function, or action of Cip/Kip family protein or a nucleic acid sequence that inhibits the production of Cip/Kip family protein, wherein the nucleic acid that inhibits the production of Cip/Kip family proteins is siRNA specific to a gene encoding the Cip/Kip family protein.

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See 37 C.F.R 1.475 (a). If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See 37 C.F.R. 1.475 (d) and 37 C.F.R 1.476 (c). For example, the invention of group I does not require proliferating cardiomyocytes comprising a step of introducing (a) cyclin, (b) cyclin-dependent kinase, and (c) one or a plurality of a gene encoding a factor that inhibits the production, function or action of Cip/Kip family protein, or a nucleic acid that inhibits the production of Cip/Kip family protein, into cardiomyocytes, in vivo, and a step of subsequently culturing said cells, wherein the nucleic acid that inhibits the production of Cip/Kip family proteins is siRNA

Art Unit: 1632

specific to a gene encoding the Cip/Kip family protein **in vitro** of group II. Accordingly, Groups I-VI are not linked by a special technical feature.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D. Art Unit 1632

DEBOATT OROUGH

Delicar Crench

DEBORAH CROUCH PRIMARY EXAMINER GROUP 1800